IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

In Re: Rosuvastatin Calcium Patent Litigation	:	MDL No. 08-1949
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Mylan Pharmaceuticals Inc., Defendant.	:	Civ. No. 07-805-JJF-LPS
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Sun Pharmaceutical Industries Ltd., Defendant.	:	Civ. No. 07-806-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 07-807-JJF-LPS
v.	:	
Sandoz Inc.,	:	
Defendant.	:	

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 07-808-JJF-LPS
v.	:	
Par Pharmaceutical Inc.,	:	
Defendant.	:	

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 07-809-JJF-LPS
v.	:	
Apotex Inc. and Apotex Corp.,	:	
Defendants.	:	

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc., Defendants.	:	Civ. No. 07-810-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc., Defendants.	:	Civ. No. 07-811-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited Inc., Defendants.	:	Civ. No. 08-359-JJF-LPS

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,	:	
Plaintiffs,	:	
	:	Civ. No. 08-426-JJF-LPS
v.	:	
Teva Pharmaceuticals USA,	:	
Defendant.	:	

REPORT AND RECOMMENDATION
REGARDING MOTIONS TO DISMISS [CORRECTED 12/22/08]

The Plaintiffs in these cases – AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca" or "Plaintiffs") – bring suit against numerous defendants (who are described in the next section) alleging patent infringement. AstraZeneca holds all substantial rights in U.S. Patent No. RE37,314 (the "'314 patent"), entitled "Pyrimidine Derivatives." Exercising its rights under the '314 patent, AstraZeneca manufactures and sells a drug under the brand name "Crestor."

Each of the multiple defendants is involved in some way with the filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"). Some or all of the defendants wish to manufacture, import, use, and/or sell generic versions of a drug that AstraZeneca alleges would infringe its '314 patent.

Now before the Court are six motions to dismiss. Despite the large number of parties and motions, the issues requiring decision at this time are just three: (i) must the Court dismiss

certain defendants because they purport to have signed an ANDA merely as an agent of the entity that actually prepared and "submitted" the application; (ii) must the Court dismiss AstraZeneca's Count II, which seeks a declaratory judgment of infringement pursuant to 35 U.S.C. § 271(a), due to the lack of a sufficiently immediate case or controversy; and (iii) does this Court have personal jurisdiction over all defendants? For the reasons explained below, I recommend that the Court deny the Submitter Motions (keeping in the case those defendants who claim only to be agents), grant the Motions to Dismiss Count II, and deny without prejudice the motions to dismiss for lack of personal jurisdiction.

PROCEDURAL AND FACTUAL BACKGROUND[1]

The Parties

Plaintiffs are corporations that, collectively, hold all substantial rights in the '314 patent. (Civ. No. 805 D.I. 1 ¶ 17) Plaintiffs also hold approved New Drug Application ("NDA") No. 021366 for rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage forms. (Civ. No. 805 D.I. 1 ¶ 7) Plaintiffs market these tablets under the brand name Crestor.

Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a West Virginia corporation with a principal place of business in West Virginia. (Civ. No. 805 D.I. 1 ¶ 6) Mylan filed with the FDA ANDA No. 79-161 seeking approval for the commercial manufacture, use, importation, offer for

[1]Other than allegations regarding jurisdiction, on which the Court must make factual findings based on the record the parties have created, *see Nesbit v. Gears Unlimited, Inc.*, 347 F.3d 72, 77 (3d Cir. 2003) (holding that with respect to jurisdiction Court need not view evidence in light most favorable to either party), and except where otherwise indicated, all factual statements in this section are based on Plaintiffs' complaints, which the Court must take as true at this point.

sale, and sale of generic versions of rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 805 D.I. 1 ¶ 10) Mylan notified AstraZeneca of its ANDA filing by letter dated November 13, 2007. (Civ. No. 805 D.I. 1 ¶ 11)[2] Mylan did not file any pretrial motions.

Defendant Sun Pharmaceutical Industries Ltd. ("Sun") is an Indian corporation with a principal place of business in India. (Civ. No. 806 D.I. 1 ¶¶ 6)[3] Sun filed with the FDA ANDA No. 79-169 seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of generic versions of rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 806 D.I. 1 ¶ 12) Sun notified AstraZeneca of its ANDA filing by letter dated November 16, 2007. (Civ. No. 806 D.I. 1 ¶ 13) Sun has filed one of the Motions to Dismiss, seeking to dismiss AstraZeneca's Count II declaratory judgment action. (Civ. No. 806 D.I. 18)

Defendant Sandoz Inc. ("Sandoz") is a Delaware corporation with a principal place of business in New Jersey. (Civ. No. 807 D.I. 1 ¶ 6) Sandoz filed with the FDA ANDA No. 79-171 seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of generic versions of rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 807 D.I. 1 ¶ 10) Sun notified AstraZeneca of its ANDA filing by letter dated November 8, 2007. (Civ. No. 807 D.I. 1 ¶ 11) Sandoz did not file any pretrial motions.

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[2]The Complaints do not allege the dates on which the various defendants filed their ANDAs. Pursuant to 21 U.S.C. § 355(c)(3)(C), an automatic 30-month stay of FDA approval of an ANDA is triggered by a patentee's filing of an infringement lawsuit within 45 days of receiving notice of the ANDA from the ANDA applicant. It is the date of the notice, and not the date of the application, that is relevant to determining the applicability of the automatic stay.

[3]Originally, Plaintiffs had also sued related entities Sun Pharmaceutical Industries Inc. and Caraco Pharmaceutical Laboratories Ltd. (Civ. No. 806 D.I. 1 ¶¶ 7-8) These defendants have since been voluntarily dismissed. (Civ. No. 806 D.I. 9)

Defendant Par Pharmaceutical, Inc. ("Par") is a Delaware corporation with a principal place of business in New Jersey. (Civ. No. 808 D.I. 1 ¶ 6) Par filed with the FDA ANDA No. 79-168 seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of generic versions of rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 808 D.I. 1 ¶ 10) Par notified AstraZeneca of its ANDA filing by letter dated November 5, 2007. (Civ. No. 808 D.I. 1 ¶ 11) Par did not file any pretrial motions.

Defendant Apotex Inc. ("Apotex Canada") is a Canadian corporation with a principal place of business in Canada. (Civ. No. 809 D.I. 1 ¶ 6) Defendant Apotex Corp. ("Apotex USA"), a Delaware corporation with a principal place of business in Florida, is alleged by Plaintiffs to be "a wholly owned subsidiary" of Apotex Canada. (Civ. No. 809 D.I. 1 ¶ 7)[4] "Apotex [Canada] and/or Apotex USA filed with the FDA . . . ANDA No. 79-145" seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of generic versions of rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 809 D.I. 1 ¶ 11) Apotex Canada notified AstraZeneca of the ANDA filing by letters dated November 5, 2007 and December 4, 2007. (Civ. No. 809 D.I. 1 ¶ 12) Apotex Canada has moved to dismiss this action for lack of personal jurisdiction or in the alternative to transfer it to the Middle District of Florida. (Civ. No. 809 D.I. 13) Apotex USA: has filed a Submitter Motion, seeking to be dismissed as a defendant on AstraZeneca's Count I since Apotex USA purportedly did not submit the ANDA; has also filed a Motion to Dismiss AstraZeneca's Count II declaratory judgment action; and asks that the entire action against it be dismissed for lack of personal

[4]The Apotex entities dispute this contention. *See* July 3, 2008 Hearing Transcript (Civ. No. 806 D.I. 50) ("Tr.") at 6.

jurisdiction and/or failure to join the necessary party of Apotex Canada. (Civ. No. 809 D.I. 16)

Defendant Aurobindo Pharma Limited ("Aurobindo India") is an Indian corporation with a principal place of business in India. (Civ. No. 810 D.I. 1 ¶ 6) Defendant Aurobindo Pharma USA Inc. ("Aurobindo USA") is alleged to be a wholly owned subsidiary of Aurobindo Pharma as well as a Delaware corporation with a principal place of business in New Jersey. (Civ. No. 810 D.I. 1 ¶ 7)[5] "Aurobindo [India] and/or Aurobindo USA filed with the FDA . . . ANDA No. 79-170" seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of generic versions of rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 810 D.I. 1 ¶ 11) Aurobindo India notified AstraZeneca of the ANDA filing by letter dated October 31, 2007. (Civ. No. 810 D.I. 1 ¶ 12) Aurobindo India has moved to dismiss for lack of personal jurisdiction. (Civ. No. 810 D.I. 17) Aurobindo USA: has filed a Submitter Motion, seeking to be dismissed as a defendant on AstraZeneca's Count I since Aurobindo USA purportedly did not submit the ANDA; has also filed a Motion to Dismiss AstraZeneca's Count II declaratory judgment action; and asks that the entire action against it be dismissed for lack of personal jurisdiction and/or failure to join the necessary party of Aurobindo India. (Civ. No. 810 D.I. 15)

Defendant Cobalt Pharmaceuticals Inc. ("Cobalt Canada") is a Canadian corporation with a principal place of business in Canada. (Civ. No. 811 D.I. 1 ¶ 6) Defendant Cobalt Laboratories Inc. ("Cobalt USA"), a Delaware corporation, "is Cobalt Pharma's sister company" and has a principal place of business in Florida. (Civ. No. 811 D.I. 1 ¶ 7) "Cobalt [Canada] and/or Cobalt USA filed with the FDA . . . ANDA No. 79-167" seeking approval for the commercial

[5]The Aurobindo entities dispute this contention. *See* Tr. at 41.

manufacture, use, importation, offer for sale, and sale in the United States of rosuvastatin calcium tablets in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 811 D.I. 1 ¶ 11) Cobalt Canada notified AstraZeneca of the ANDA filing by letter dated October 31, 2007. (Civ. No. 811 D.I. 1 ¶ 12) Cobalt Canada and Cobalt USA have filed Motions to Dismiss AstraZeneca's Count II § 271(a) declaratory judgment action. (Civ. No. 811 D.I. 14)

The ANDA Approval And Litigation Process

The Supreme Court and the Federal Circuit have had occasion to describe the history of what has come to be known as the "Hatch-Waxman Act,"[6] which established the ANDA procedures out of which these cases arise. Here, too, "a brief review of that history will shed some light on the proper interpretation" of the statutory provisions at issue. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003).

As the Federal Circuit recently explained:

> Under federal law at the time the [Hatch-Waxman] Act was negotiated and signed into law, a patent "granted to the patentee, his heirs, or assigns, for the term of seventeen years . . . the right to exclude others from making, using, or selling the invention throughout the United States." . . . .
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> [T]he Act was designed to respond to two problems that the patent and pharmaceutical regulatory statutes were perceived to have led to by the 1980s. One of those problems arose from the fact that an inventor ordinarily applies for patent protection for newly discovered drugs, or for methods for the use of new or existing drugs, well before securing regulatory approval, even though it generally cannot legally market such products or promote their use until it obtains that approval. Since the FDA generally took much longer to approve an NDA than the United States Patent and Trademark Office took to grant a patent, a manufacturer's patent term was substantially eroded by the time the patentee was able to derive

[6]Pub. L. No. 98-417, 98 Stat. 1585 (1984), the "Drug Price Competition and Patent Term Restoration Act of 1984," codified at 21 U.S.C. § 355 & 35 U.S.C. § 271(e).

any profit from the invention.

The second problem inhered in the need for a generic manufacturer to obtain its own NDA if it wanted to market a product. A new NDA required the generic company to provide its own safety and efficacy data, which it was argued was a waste of resources. This need was complicated by the assumption . . . that the plain language of [35 U.S.C.] § 271(a) made the manufacture and testing (a use) of a patented product prior to the expiration of the patent an act of infringement, even if that manufacture or use was solely for the purpose of conducting tests and developing the necessary information to apply for regulatory approval later on. Because it took a substantial amount of time for a second or subsequent manufacturer to obtain data and secure regulatory approval, requiring those manufacturers to wait until after the expiration of the patent to begin testing and other pre-approval activities resulted in a *de facto* extension of the patent term. The Hatch-Waxman Act intended to deal with both of these issues, *i.e.*, to restore to innovators patent time lost during testing and regulatory approval, but to enable generic manufacturers to be ready to enter the market once patents expired. The latter no longer would have to prove the safety and efficacy of a drug that was already the object of an NDA; they would just have to prove bioequivalence [to the already approved drug].

Section 201 of the Act, codified at 35 U.S.C. § 156, accordingly provided for patent term extension for [a] product[] "subject to a regulatory review period before its commercial marketing or use," if "the permission for the commercial marketing or use of the product after such regulatory review period [was] the first permitted commercial marketing or use of the product."

Section 202 of the Hatch-Waxman Act added to 35 U.S.C. § 271 a new subsection, (e)(1), on the other hand, that provided that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." Section 271(e)(1) thus partially eliminated the second problem, *i.e.*, the *de facto* unintended extension of the patent term, and enabled generic manufacturers to test and seek approval to market during the patent term. To further the overall goals of the Act, § 101 also amended § 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. § 355, to authorize the filing and approval of ANDAs. Included in the ANDA provisions was a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator's drugs. That mechanism included, *inter alia*, provision for patentees and NDA holders to list patents that claim the approved drug or the approved use of the drug; and provision for ANDA applicants to "certify": (I) that no such patent information is listed, or, if such information is listed, then, for each listed patent, (II) that it has

> expired, (III) that it will expire prior to the ANDA applicant's marketing of the drug, or (IV) that it is invalid or will not be infringed by the manufacture, use, or sale of the drug by the ANDA applicant, 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). The ANDA provisions now codified at 35 U.S.C. § 271(e)(2)(A) also created an artificial act of infringement that consists of submitting an ANDA containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that a listed patent is invalid or that the manufacture, sale, or use of the proposed product would not infringe that patent.
>
> The Hatch-Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by similar regulatory requirements.

Id. at 1356-59 (internal citations and footnotes omitted).

Several components of the regulatory-judicial regime established by the Hatch-Waxman Act require further elaboration here. First is the "Orange Book," the shorthand title for the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," which lists "the number and expiration date of any patent which claims [a] drug" that is the subject of a "[p]ioneer drug applicant['s]" NDA "or a method of using such drug." *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990) (citing 21 U.S.C. § 355(b)(1)); *see also* 21 C.F.R. § 314.53(e). It is undisputed here that AstraZeneca listed the '314 patent, which does not expire until January 2016, in the Orange Book.[7]

Second, when a generic drug company files an ANDA and certifies that its approval should not be hindered by the existence of a patent listed in the Orange Book, such a certification may involve – as it does here – a "Paragraph IV Certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A Paragraph IV Certification requires an assertion, and supporting

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[7]*See generally* "Electronic Orange Book," Appl. No. 021366, at www.fda.gov/cder/ob.

explanation, that the listed patent is invalid or would not be infringed by the generic company's manufacture and sale of its proposed drug. As the Supreme Court has explained: "An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed." *Eli Lilly*, 496 U.S. at 677. Here it is undisputed that each defendant or set of defendants sent Plaintiffs a timely and adequate Paragraph IV Certification.

Third, the Hatch-Waxman Act makes the filing of an ANDA containing a Paragraph IV Certification an act of patent infringement. *See* 35 U.S.C. § 271(e)(2). The Supreme Court stated: "The function of the paragraph[] in question is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications." *Eli Lilly*, 496 U.S. at 676. The Court added:

> This [Hatch-Waxman] scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new 35 U.S.C. § 271(e)(1) imposed with regard to use of his patented invention only for the purpose of obtaining premarketing approval. Thus, an act of infringement had to be created for these ANDA . . . proceedings. That is what is achieved by § 271(e)(2) - the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing the [Paragraph IV] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in subsection (e)(4). Monetary damages are permitted only if there has been "commercial manufacture, use, or sale." Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA . . . schemes depend.

Id. at 678.

Fourth, a patent holder in receipt of a Paragraph IV Certification which files a patent infringement lawsuit against the ANDA applicant within 45 days of receipt of the certification obtains an automatic stay of FDA approval of the ANDA until the earlier of the completion of the lawsuit or the expiration of 30 months. *See id.* at 677-78. These timing provisions are part of a design which aims to provide relatively expeditious resolution of disputes relating to the relevant patents listed in the Orange Book, thereby helping to protect the return on investment pioneer companies need to justify their research expenditures, while at the same time accelerating the pace by which less expensive, generic drugs may reach the market. *See generally Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 321 F. Supp.2d 612, 617 (D. Del. 2004) ("[T]he purposes of the Hatch-Waxman Act [include] to make low-cost generic drugs more available and create new incentives for research and development of certain products which are subject to premarket approval."). Here, there is no dispute that AstraZeneca filed its actions in time to trigger the automatic 30-month stay.

Fifth, FDA regulations specify the content and format of the ANDA application. In particular, the FDA requires that when "the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States." 21 C.F.R. § 314.94(a)(1) (incorporating requirements of 21 C.F.R. § 314.50(a)(5)). Similarly, the FDA requires that the notice letter containing the Paragraph IV Certification sent to the patentholder include "the name

and address of an agent in the United States authorized to accept service of process for the applicant," if the applicant does not reside in or have a place of business in the United States. 21 C.F.R. § 314.95(c)(7).

The Instant Litigation

On December 11, 2007, within 45 days of receiving the Defendants' notice letters containing Paragraph IV Certifications, AstraZeneca filed suit against each of the Defendants. (Civ. Nos. 07-805 to 07-811 D.I. 1) Each complaint consists of two counts. Count I is an ANDA infringement action, brought pursuant to 35 U.S.C. § 271(e)(2)(A), by which AstraZeneca seeks a ruling that Defendants' ANDA filings constitute an "artificial act" of infringement because the generic products Defendants seek to market would infringe AstraZeneca's '314 patent. Two Defendants – Apotex USA and Aurobindo USA – seek dismissal of Count I as against them, on the grounds that these two Defendants signed the ANDAs merely as agents and, therefore, did not actually "submit" the applications ("Submitter Motions").

Count II is an ordinary patent infringement action, brought pursuant to 35 U.S.C. § 271(a), by which AstraZeneca seeks a declaratory judgment that Defendants' proposed manufacture, import, use, and sale of a generic version of Crestor would infringe the '314 patent. That is, AstraZeneca alleges that Defendants' actions violate the ordinary prohibition on patent infringement – and do not merely constitute the artificial act of infringement created by the Hatch-Waxman Act and codified in Section 271(e). Defendants Sun, Apotex USA, Aurobindo USA, and Cobalt move to dismiss Count II for lack of subject matter jurisdiction due to what

they claim is the absence of a sufficiently immediate case or controversy ("Motions to Dismiss").

Finally, Defendants Apotex Canada and Aurobindo India claim that this Court lacks personal jurisdiction over them with respect to Counts I and II ("Personal Jurisdiction Motions").

Actions Resulting In Consolidated MDL

In addition to the seven actions AstraZeneca filed in this District, related actions have been filed elsewhere. On December 18, 2007, AstraZeneca filed suit against Aurobindo India and Aurobindo USA in the District of New Jersey, asserting the same causes of action it has asserted against these parties here. (D.N.J. C.A. 3:07-6020; *see also* D. Del. Civ. No. 08-359) On January 31, 2008, Defendant Apotex Canada filed suit against AstraZeneca in the Middle District of Florida, seeking a declaratory judgment of non-infringement of another patent AstraZeneca has listed in the Orange Book as relating to Crestor. (M.D. Fl. C.A. 8:08-213; *see also* D. Del. Civ. No. 08-358)[8]

Thereafter, AstraZeneca moved, pursuant to 28 U.S.C. § 1407, to centralize all litigation relating to the ANDAs and the '314 patent here in Delaware. (M.D.L. No. 1949) The matter was reviewed by the United States Judicial Panel on Multidistrict Litigation ("MDL Panel"). On June 13, 2008, the MDL Panel held that "[c]entralization under Section 1407 will eliminate duplicative discovery, prevent inconsistent pretrial rulings (particularly on claim construction issues), and conserve the resources of the parties, their counsel and the judiciary." (Civ. No. 08-1949 D.I. 1 at 1) The MDL Panel further stated that "centralization will place all actions in this

[8]The Florida action relates to U.S. Patent No. 6,316,460, for which AstraZeneca is the owner and/or assignee. (Civ. No. 08-358 D.I. 22)

docket before a single judge who can structure pretrial proceedings to accommodate all parties' legitimate discovery needs while ensuring that the common parties and witnesses are not subjected to discovery demands that duplicate activity." *Id.* at 2. Thus, the MDL Panel ordered that AstraZeneca's New Jersey action and Apotex Canada's Middle District of Florida action be transferred to this District "for coordinated or consolidated pretrial proceedings" with the seven actions already pending here. *Id.*

Additional Procedural Developments

Each of these cases are assigned to Judge Farnan. He has referred each of them to me for all purposes through and including the pretrial conference. *See, e.g.*, Civ. No. 805 D.I. 9. On July 3, 2008, I held oral argument on all pending motions.

Subsequently, on July 10, 2008, AstraZeneca filed suit against Teva Pharmaceuticals USA, a Delaware corporation with a principal place of business in Pennsylvania. (Civ. No. 08-426 D.I. 1 ¶ 6) Teva had filed ANDA No. 79-166 seeking to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale of generic versions of rosuvastatin in 5, 10, 20, and 40 mg dosage strengths. (Civ. No. 08-426 D.I. 1 ¶ 10) Teva had notified AstraZeneca of its ANDA filings on October 29, 2007 and June 11, 2008. (Civ. No. 08-426 D.I. 1 ¶¶ 11-12) AstraZeneca asserts the same counts – seeking a ruling of infringement of the '314 patent in violation of § 271(e) in Count I and a declaratory judgment of infringement of the '314 patent in violation of § 271(a) in Count II – as it does in the other seven complaints filed here in December 2007. Teva has filed no pretrial motions.

On September 16, 2008, Apotex Canada voluntarily dismissed the action it had originally

filed in the Middle District of Florida. (Civ. No. 08-358 D.I. 30)

LEGAL STANDARDS

Motion to Dismiss – Rule 12(b)(6)

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, "[t]o survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1965 (2007)). While heightened fact pleading is not required, "enough facts to state a claim to relief that is plausible on its face" must be alleged. *Twombly*, 127 S. Ct. at 1974. At bottom, "[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media Technology Charter School Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted). Nor is the Court

obligated to accept as true "bald assertions," *Morse v. Lower Merion School Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

Motion to Dismiss – Rule 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter. *See Samsung Electronics Co., Ltd. v. ON Semiconductor Corp.*, 541 F. Supp.2d 645, 648 (D. Del. 2008). Motions brought under Rule 12(b)(1) may present either facial or factual challenges to the Court's subject matter jurisdiction.

> In reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply. In this regard, the Court must accept all factual allegations in the Complaint as true, and the Court may only consider the complaint and documents referenced in or attached to the complaint. *Gould Electronics, Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). [In contrast, however,] [i]n reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint, and the presumption of truthfulness does not attach to the allegations in the complaint. *Mortensen v. First Fed. Sav. & Loan*, 549 F.2d 884, 891 (3d Cir. 1997). Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997).

Id.

Once the Court's subject matter jurisdiction over a complaint is challenged, Plaintiff bears the burden of proving that jurisdiction exists. *Mortensen*, 549 F.2d at 891. "Dismissal for lack of subject-matter jurisdiction because of the inadequacy of the federal claim is proper only when

the claim is so insubstantial, implausible, foreclosed by prior decisions of [the Supreme Court], or otherwise completely devoid of merit as not to involve a federal controversy." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998) (internal quotation marks omitted).

Motion to Dismiss – Rule 12(b)(2)

Federal Rule of Civil Procedure 12(b)(2) directs the Court to dismiss a case when it lacks personal jurisdiction over the defendant. Once this jurisdictional defense has been raised, the plaintiff bears the burden of establishing, with reasonable particularity, that sufficient minimum contacts have occurred between the defendant and the forum to support personal jurisdiction. *See Provident Nat'l Bank v. California Fed. Sav. & Loan Ass'n*, 819 F.2d 434, 437 (3d Cir.1987). To meet this burden, the plaintiff must produce "sworn affidavits or other competent evidence," since a Rule 12(b)(2) motion "requires resolution of factual issues outside the pleadings." *Time Share Vacation Club v. Atlantic Resorts, Ltd.*, 735 F.2d 61, 67 n.9 (3d Cir. 1984).

DISCUSSION

I. The Submitter Motions

In Count I, AstraZeneca asserts that Defendants have committed patent infringement, in violation of 35 U.S.C. § 271(e), by virtue of filing their ANDAs with the FDA. Defendants Apotex USA and Aurobindo USA (together the "Submitter Defendants") seek to dismiss Count I because, they claim, they did not "submit" the ANDAs. The Submitter Defendants assert that although they signed the ANDAs, they did so merely as agents on behalf of their foreign counterparts (Apotex Canada and Aurobindo India). They claim it is these foreign entities who

were the actual ANDA "applicants" and these entities, alone, who are subject to suit. The Submitter Defendants conclude that AstraZeneca has failed to state a claim that they have violated § 271(e) and, pursuant to Fed. R. Civ. P. 12(b)(6), Count I must be dismissed as to them.[9]

AstraZeneca disagrees, citing decisions from two other courts that rejected almost precisely the same challenge to § 271(e) actions. AstraZeneca also focuses on the certifications the Submitter Defendants made when they signed the ANDAs and the responsibilities these defendants thereby assumed.

In reviewing the Submitter Motions, the first step is to consider the language of the relevant statute. *See generally VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1579 (Fed. Cir. 1990) ("It is axiomatic that statutory interpretation begins with the language of the statute."). Section 271(e)(2)(A) provides:

It shall be an act of infringement to submit an application under section 505(j) of

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[9]In its written submissions relating to the "submitter" issue, Apotex USA invoked only Rule 12(b)(6). *See, e.g.*, Civ. No. 809 D.I. 17 at 3 ("Count I of the Complaint . . . fails to state a claim against Apotex [USA] upon which relief can be granted . . . ."); Civ. No. 809 D.I. 38 at 1. In its submissions, Aurobindo USA argued that the "submitter" issue is to be resolved pursuant to Rule 12(b)(1), since it "implicates this Court's subject matter jurisdiction." Civ. No. 810 D.I. 33 at 9; *see also* Civ. No. 810 D.I. 16 at 7. Defendants' position on the applicable rule became more complicated at the hearing, during which Apotex USA asserted that its motion arises under both Rule 12(b)(6) and Rule 12(b)(1), *see* Tr. at 33-35, while Aurobindo USA continued to insist that only 12(b)(1) applies, *see id.* at 40-41. Plaintiffs have consistently treated the Submitter Motions as arising under Rule 12(b)(6), claiming that consideration of any materials outside the pleadings would transform them into motions for summary judgment governed by Rule 56, which would be premature at this point. *See* Civ. No. 810 D.I. 30 at 4-5; Tr. at 46. I conclude that the Submitter Motions are to be evaluated pursuant to the standards of Rule 12(b)(6), as Apotex USA originally contended, and as other courts addressing the same issue have done. *See Wyeth v. Lupin Pharmaceuticals, Inc.*, 505 F. Supp.2d 303, 304 (D. Md. 2007) (treating same challenge as presented here as a 12(b)(6) motion); *Aventis Pharma Deutschland GmBH v. Lupin, Ltd.*, 403 F. Supp.2d 484, 491 (E.D. Va. 2003) (same).

> the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(Emphasis added) Plaintiffs and the Submitter Defendants are in agreement that the statute makes the act of submitting the ANDA the infringing act, so that liability extends only to those who "submit" an ANDA. *See, e.g.*, Tr. at 38, 43. The question then becomes: what does it mean to "submit" an ANDA?

The Hatch-Waxman Act does not provide a definition of "submit." *See generally Aventis*, 403 F. Supp.2d at 492 ("[T]he statute, by its terms, does not limit 'submit' to the ANDA applicant alone."). "When a statute does not define a given word or phrase, [the Court must] presume that Congress intended the word or phrase to have its ordinary meaning." *Warner-Lambert*, 316 F.3d at 1355. The parties have offered no argument as to the ordinary meaning of the word "submit" nor supplied any source of definition. I have also found no help in dictionary definitions. *See, e.g.*, *Merriam-Webster's Desk Dictionary* at 541 (1995) (defining "submit" as "to commit to the discretion or decision of another or others"); *Oxford American Desk Dictionary and Thesaurus* at 834 (2d ed. 2002) (defining "submit" as "present for consideration" or "offer, proffer, tender, put in, advance, put forward; hand or give in").

Because the plain language of the statute does not resolve the dispute, it is necessary to consider congressional intent. "In interpreting statutes, [courts] give effect to the intent of Congress by look[ing] not only to the particular statutory language, but to the design of the statute as a whole and to its object and policy." *In re Swanson*, 540 F.3d 1368, 1374-75 (Fed. Cir. 2008) (internal quotation marks omitted). In my view, congressional intent is best fostered

by interpreting "submit" to include the actions alleged to have been taken here by Apotex USA and Aurobindo USA. *See generally F. Hoffman-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 174 (2004) ("If the statute's language reasonably permits an interpretation consistent with [Congressional] intent, we should adopt it.").

Congress intended by the Hatch-Waxman Act to promote the relatively expeditious resolution of patent disputes that relate to the development and marketing of generic drugs. *See Aventis*, 403 F. Supp.2d at 487 ("Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible . . . ."). Congress did not want generic drugs to reach the market too soon (i.e., before the expiration of a valid patent that would thereby be infringed) nor kept from the market unnecessarily (due to incessant litigation or delays in completing research that could not even begin until after the expiration of the patent). These goals are furthered by treating a wholly-owned subsidiary of a foreign ANDA applicant, which signs an ANDA as the agent of its parent-applicant, and which intends to benefit directly if the ANDA is approved – by participating in the manufacture, importation, distribution, and/or sale of the generic drug – as subject to suit under § 271(e) as one who has "submitted" an ANDA.

Weighing heavily in favor of this holding are the representations the Submitter Defendants made by signing the ANDAs. As AstraZeneca notes, "[s]igning the ANDA required certifying under threat of criminal prosecution as to the truth and accuracy of the information presented to the FDA and a promise to, among other things, update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling." (Civ. No.

810 D.I. 30 at 8) (internal quotation marks omitted). While the Submitter Defendants insist that they lacked the knowledge or resources to complete an ANDA, *see, e.g.*, Civ. No. 810 D.I. 16 at 10-11, AstraZeneca, in deciding whom to sue for patent infringement under § 271(e), was entitled to rely on the arguably contrary representations these two entities made by signing the ANDAs. To hold otherwise might require a patent holder in AstraZeneca's position to engage in a perhaps extensive investigation to figure out whom to sue.[10] Even assuming it were possible for patentees to undertake the type of pre-suit investigation the Submitter Defendants suggest is required,[11] patentees likely would struggle to do so within the time constraints imposed by Hatch-Waxman. To obtain the automatic thirty-month stay, the patentee must file suit within 45 days of receiving the notice letter. To hold that a patentee may not rely on the agent's signature on the ANDA, but must instead determine before filing suit the precise role such a signatory had in the preparation of the ANDA, could regularly deprive patentees of the automatic stay Congress

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[10]It seems more likely that Congress intended patentees, in deciding whom to sue, to be able to rely on the entities identified in the ANDAs and in the notice letters, just as generic drug manufacturers may rely on the Orange Book listings to determine to whom notice letters must be sent.

[11]Plaintiffs plead: "On information and belief, Aurobindo USA, as the authorized agent of Aurobindo [India] and/or in its own capacity, participated in the preparation . . . of the Aurobindo ANDA . . . ." Civ. No. 810 D.I. 1 ¶ 14; *see also* Civ. No. 809 D.I. 1 ¶ 14 (alleging Apotex USA "participated in" preparation of Apotex ANDA). On a Rule 12(b)(6) motion to dismiss, the Court must take these allegations as true. Nonetheless, Apotex USA and Aurobindo USA deny them, asserting that they had nothing to do with the preparation of the respective ANDAs. (Civ. No. 809 D.I. 38 at 5; Civ. No. 810 D.I. 16 at 5-6) During oral argument, Aurobindo's counsel suggested that AstraZeneca should have determined prior to filing suit "Who did the work [on the ANDA]? Who's going to benefit from the application? Who is the party who understands the technology, can make the drug, is going to provide the drug to the U.S. market?" Tr. at 38. But AstraZeneca did not necessarily have a way of making these determinations when it received the notice letters from Apotex and Aurobindo. Answering these questions may well have required discovery, which AstraZeneca could not obtain until after it filed suit.

provided for, thus imposing a burden on patentees that would be inconsistent with the Hatch-Waxman framework. To the extent such a holding would slow down ANDA litigation, it would, for this reason too, be contrary to "the statutory scheme of the Hatch-Waxman Act [which] relies on early resolution of patent disputes." *Teva Pharmaceuticals USA v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007).

My conclusions are in accord with those of the two courts that have considered this same question and have held that entities similarly-situated to Apotex USA and Aurobindo USA have "submitted" an ANDA. *See Wyeth*, 505 F. Supp.2d at 306-07 ("[W]hen a wholly-owned U.S. subsidiary of a foreign corporation exists to distribute foreign-produced generic drugs in the U.S. and is actively involved in the ANDA process, the subsidiary also 'submits' an ANDA application."); *Aventis*, 403 F. Supp.2d at 492-94 (permitting § 271(e)(2) claims to proceed against foreign parent as well as against its wholly-owned U.S. subsidiary that countersigned ANDA and appeared to be parent's U.S. marketing arm).

The Submitter Defendants seek to distinguish the applicability of these cases because in each of them the American co-signing entity was a wholly-owned subsidiary of the foreign ANDA applicant, while the Submitter Defendants claim they are not. *See* Tr. at 6 (counsel explaining Apotex USA "is not a U.S. subsidiary. It's a separately incorporated corporation."); *id.* at 41 (counsel explaining Aurobindo USA "is a subsidiary" of Aurobindo India "but it's a separate corporate entity"). But the complaints allege that Apotex USA is a "wholly owned subsidiary" of Apotex Canada (Civ. No. 809 D.I. 1 ¶ 7) and Aurobindo USA is a "wholly owned subsidiary" of Aurobindo India (Civ. No. 810 D.I. 1 ¶ 7). On reviewing the Submitter Motions, I must take as true all material allegations in the complaints.

The Submitter Defendants insist that they merely signed the applications as agents for their foreign counterparts, as is required by regulation whenever an ANDA applicant is a foreign entity. In this regard, the Submitter Defendants analogize themselves to an attorney representing a client, explaining that no one would conclude an attorney signatory would be subject to suit as one who has "submitted" an ANDA. *See, e.g.*, Civ. No. 810 D.I. 33 at 4. Again, however, the representations the Submitter Defendants made when signing the ANDAs are inconsistent with those that would be made by an unknowing agent, and AstraZeneca was entitled to rely on these representations. That the Submitter Defendants signed the ANDAs because regulations required them to do so does not detract from the significance of the act of signing (and arguably enhances that significance). The Submitter Defendants are distinguished from attorneys signing as mere agents because they are alleged to be wholly-owned subsidiaries of the foreign "applicants," are alleged to have participated in the preparation of the ANDAs, and are alleged to be involved in "marketing, distributing, and selling generic pharmaceutical products within the United States" in concert with their foreign counterparts. (Civ. No. 809 D.I. 1 ¶¶ 7, 13, 14; Civ. No. 810 D.I. 1 ¶¶ 7, 13, 14) *See also Wyeth*, 505 F. Supp.2d at 306-07 (noting same distinctions).

Finally, the cases on which the Submitter Defendants rely are distinguishable. *See SmithKline Beecham Corp. v. Geneva Pharmaceuticals., Inc.*, 287 F. Supp.2d 576 (E.D. Pa. 2002) (denying motion to amend complaint because proposed infringement claim would be futile under standards applicable to Rule 12(b)(6) motions); *SmithKline Beecham Corp. v. Pentech Pharmaceuticals., Inc.*, 2001 WL 184804 (N.D. Ill. Feb. 20, 2001) (same). In each of these cases, the entities that successfully opposed ANDA actions were unrelated third-party manufacturers of the active ingredient for the proposed generic drugs and did not sign the

applications. *See Aventis*, 403 F. Supp.2d at 492 ("Unlike *Geneva* and *Pentech*, this is not a case where a third-party manufacturer uninvolved in the submission of the ANDA is included as a party; rather, this case involves a *subsidiary* of the applicant and that subsidiary *submitted* the ANDA application to the FDA as *agent* on the foreign company's behalf.").

Thus, I recommend that the Submitter Motions be denied.

II. The Motions To Dismiss Count II

In addition to filing a standard ANDA patent infringement action pursuant to § 271(e), in Count II AstraZeneca has filed a non-ANDA patent infringement declaratory judgment action pursuant to § 271(a). Four sets of Defendants – Sun, Apotex, Aurobindo, and Cobalt (collectively the "Moving Defendants") – move to dismiss Count II on the grounds that there is no "actual controversy" that is "sufficiently immediate to justify jurisdiction under 271(a)." Tr. at 11.

As the Supreme Court has recently explained, declaratory judgment jurisdiction in a patent case requires the Court to consider whether the "facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (internal quotation marks omitted). According to the Moving Defendants, declaratory judgment jurisdiction is lacking here because there is no sufficiently immediate controversy between AstraZeneca and themselves. This is because, under Hatch-Waxman, AstraZeneca's filing of Count I stayed FDA approval of all Defendants' ANDAs. Tr. at 13-14. Furthermore, the Moving Defendants point out, all of the

activity they engaged in to prepare their ANDAs came within the "safe harbor" of § 271(e)(1); to "eviscerate[]" this protection would "revers[e]" Congress' intentions. Tr. at 12, 30. Finally, the Moving Defendants observe that the entirety of the relief AstraZeneca seeks by its § 271(a) action is relief already available to AstraZeneca if it prevails on its § 271(e) action, and this "redundancy" is yet another basis for rejecting Count II. Tr. at 17-18.

I agree with the Moving Defendants that Count II should be dismissed. As has already been described, the Hatch-Waxman Act establishes an elaborate and specific framework for promoting expeditious resolution of patent disputes relating to ANDA filings. Nothing in the Hatch-Waxman Act appears to contemplate that a patentee, at the same time it pursues the § 271(e) action created for it by the Act, would also pursue an ordinary § 271(a) patent infringement action on the same patent and based on all the same facts.

There is not at present a controversy of "sufficient immediacy" between AstraZeneca and the Moving Defendants to permit a declaratory judgment to be awarded under § 271(a). The filing of these lawsuits triggered the automatic 30-month stay of FDA approval of each of Defendants' ANDAs. The Defendants cannot manufacture, import, market, or sell their proposed generic drug in the United States without FDA approval, but FDA approval cannot come until the earlier of the expiration of the stay or the conclusion of this litigation. Absent further order of the Court, the stay will remain in place until ~~June 2010~~ [CORRECTION February 2011]; trial in this action is not scheduled to occur until February 2010. Hence, today – in November 2008 – there is simply no sufficient immediacy to the controversy AstraZeneca seeks to press in its Count II.

Moreover, to permit the § 271(a) action to proceed seems to me to be inconsistent with Congressional intent. Congress evidently believed that a patentee in AstraZeneca's position did

not have a cause of action under § 271(a) – indeed, the lack of such an action was a motivating factor in creating the § 271(e)(2) action. Second, the § 271(e)(1) "safe harbor" would be threatened if a patentee could sue ANDA filers under § 271(a) for conduct (such as preparing an ANDA) that is expressly identified in the Act as "not . . . an act of infringement."

Additionally, the controversy AstraZeneca wants resolved – whether Defendants' proposed generic drugs would infringe a valid '314 patent – will be resolved through disposition of its § 271(e) count. There is no relief Plaintiffs could be awarded by prevailing on Count II that they would not also be able to obtain if they prevail on Count I.[12]

Plaintiffs assert there is no authority that precludes them from bringing a § 271(a) action, *see* Tr. at 21, and they are correct. On the other hand, there is also no case expressly considering whether both types of actions may be maintained simultaneously and concluding that this may be done. Plaintiffs further argue that the overriding goal of the Hatch-Waxman Act is to provide "patent certainty," which may only be achieved here by permitting the § 271(a) count to proceed. Tr. at 22. I believe, however, that Plaintiffs will achieve sufficient patent certainty – and, more importantly, all the certainty the law provides them – through resolution of their § 271(e) count. At the conclusion of the § 271(e) action, all will know whether or not Defendants' intended entry

[12]AstraZeneca argues that a § 271(a) injunction is broader than § 271(e) injunction in that the former "would prohibit all forms of infringement of the '314 patent, whether or not associated with this ANDA." *E.g.*, Civ. No. 806 D.I. 26 at 13. But there is no basis at this time to believe that any of the Defendants have any intention to engage in any conduct that could even arguably constitute infringement other than in connection with the pending ANDAs. Declaratory judgment jurisdiction may not be predicated on pure speculation. *See Dodge-Regupol, Inc. v. RB Rubber Products, Inc.*, __ F. Supp.2d __, 2008 WL 4868632, at *4 (M.D. Pa. Nov. 12, 2008).

into the market for rosuvastatin calcium tablets will infringe a valid patent.[13] Plaintiffs' contention that several Defendants' counterclaims for a declaratory judgment of non-infringement of the '314 patent constitute an acknolwedgement that there is a sufficiently immediate controversy, *see, e.g.*, Civ. No. 806 D.I. 26 at 4-5; Civ. No. 810 D.I. 30 at 10-11, likewise misses the mark. These counterclaims are asserted under § 271(e), not § 271(a). *See, e.g.*, Civ. No. 806 D.I. 29 at 1-2; Civ. No. 810 D.I. 33 at 10.

For the foregoing reasons, I recommend that the Motions to Dismiss be granted.[14]

III. The Personal Jurisdiction Motions

Defendants Apotex Canada and Aurobindo India have filed the Personal Jurisdiction Motions, seeking to be dismissed from this case due to the District of Delaware's purported lack of personal jurisdiction over these two Defendants. Subsequent to the filing of the Personal Jurisdiction Motions, the MDL Panel granted AstraZeneca's motion to centralize the litigation relating to the '314 patent in this District "for coordinated or consolidated pretrial proceedings." (Civ. No. 08-1949 D.I. 1) The MDL Panel order directs that pretrial proceedings in the Apotex

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[13]To the extent AstraZeneca's concern is that any relief this Court might grant on the § 271(e) count will not apply to Apotex USA and Aurobindo USA, *see* Tr. at 23, this will not remain even a potential issue if my recommendation that the Submitter Motions be denied is adopted.

[14]In only four of the seven actions did defendants move to dismiss Count II.. Since the Court has an independent obligation to examine the basis for its jurisdiction, *see, e.g.*, *Salmon Spawning & Recovery Alliance v. United States*, 532 F.3d 1338, 1351 n.12 (Fed. Cir. 2008), the lack of a motion in the three remaining actions is not dispositive. Having found there is an insufficiently immediate controversy between AstraZeneca and the defendants in these four actions, and given that there is no material difference in the circumstances presented in the other three actions, I recommend that Count II be dismissed in all seven actions. Counsel appear to agree. Tr. at 27-29.

and Aurobindo cases occur in the District of Delaware, making the issue of this Court's personal jurisdiction over these defendants – at least for all purposes prior to trial – moot.

Hence, it is most efficient, equitable, and proper to defer any analysis of the arguments over personal jurisdiction until such time as their resolution might have some impact on where proceedings will actually take place. If Apotex Canada or Aurobindo India continue to believe that personal jurisdiction is lacking in this District as trial approaches, they should assert this issue again at a later date.

Accordingly, I recommend that the Personal Jurisdiction Motions be denied without prejudice to Apotex Canada's and Aurobindo India's right to renew these motions in time to be resolved at the pretrial conference.[15]

RECOMMENDED DISPOSITION

For the reasons set forth above, I recommend that the Submitter Motions be DENIED, the Motions to Dismiss Count II for lack of subject matter jurisdiction be GRANTED, and the Personal Jurisdiction Motions be DENIED WITHOUT PREJUDICE. In particular, I recommend that:

1. In Civ. No. 07-806, Sun Pharmaceutical Industries Ltd.'s Motion to Dismiss for Lack of Jurisdiction Over the Subject Matter (D.I. 18) be GRANTED.

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[15]Apotex USA moves to dismiss the complaint against it pursuant to Fed. R. Civ. P. 12(b)(7) due to failure to join the necessary party of Apotex Canada. Likewise, Aurobindo USA moves to dismiss the complaint against it pursuant to Rule 12(b)(7) due to failure to join the necessary party of Aurobindo India. Because I recommend denying the Personal Jurisdiction Motions, Apotex Canada and Aurobindo India remain parties to these actions. Accordingly, there is no need to reach the Rule 12(b)(7) issue.

2. In Civ. No. 07-809, (a) Apotex Inc.'s Motion to Dismiss for Lack of Jurisdiction Over the Person (D.I. 13) be DENIED WITHOUT PREJUDICE, and (b) Apotex Corp.'s Motion to Dismiss for Failure to State a Claim (D.I. 16) be DENIED to the extent it seeks to dismiss Count I against Apotex Corp., be GRANTED to the extent it seeks to dismiss Count II, and be DENIED WITHOUT PREJUDICE to the extent it seeks to dismiss the entire action for lack of personal jurisdiction or failure to join a necessary party.

3. In Civ. No. 07-810, (a) Aurobindo Pharma USA Inc.'s Motion to Dismiss the Complaint for Lack of Subject Matter Jurisdiction (D.I. 15) be DENIED to the extent it seeks to dismiss Count I and be GRANTED to the extent it seeks to dismiss Count II, and (b) Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc.'s Motion to Dismiss for Lack of Personal Jurisdiction and Nonjoinder (D.I. 17) be DENIED WITHOUT PREJUDICE.

4. In. Civ. No. 07-811, Cobalt Laboratories Inc. and Cobalt Pharmaceuticals Inc.'s Motion to Dismiss Count II of the Complaint or Terminate the Automatic Stay of Approval (D.I. 14) be GRANTED to the extent it seeks to dismiss Count II.

5. It is further recommended that Count II be DISMISSED against all Defendants.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within ten (10) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir.1987); *Sincavage v. Barnhart*, 171 Fed. Appx. 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order In Non-Pro Se Matters For Objections Filed Under Fed. R. Civ. P. 72, dated April 7, 2008, a copy of which is available on the Court's website, www.ded.uscourts.gov/StandingOrdersMain.htm.

Dated: November 24, 2008

[CORRECTED 12/22/2008]

Honorable Leonard P. Stark
UNITED STATES MAGISTRATE JUDGE